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UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.53(b))	Attorney Docket No.	20037
	First Inventor or Application Identifier	Oscar Jimenez
	Title	Catheter With Thermoresponsive Distal Tip
	Express Mail Label No.	EL 468140038 US

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents.	ADDRESS TO: Assistant Commissioner for Patents Box Patent Application Washington, DC 20231
1. <input checked="" type="checkbox"/> * Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original, and a duplicate for fee processing)	6. <input type="checkbox"/> Microfiche Computer Program (Appendix)
2. <input checked="" type="checkbox"/> Specification [Total Pages 9] (preferred arrangement set forth below) <ul style="list-style-type: none">- Descriptive title of the Invention- Cross References to Related Applications- Statement Regarding Fed sponsored R & D- Reference to Microfiche Appendix- Background of the Invention- Brief Summary of the Invention- Brief Description of the Drawings (if filed)- Detailed Description- Claim(s)- Abstract of the Disclosure	7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) <ul style="list-style-type: none">a. <input type="checkbox"/> Computer Readable Copyb. <input type="checkbox"/> Paper Copy (identical to computer copy)c. <input type="checkbox"/> Statement verifying identity of above copies
3. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets 1]	ACCOMPANYING APPLICATION PARTS <ul style="list-style-type: none">8. <input type="checkbox"/> Assignment Papers (cover sheet & document(s))9. <input type="checkbox"/> 37 C.F.R. §3.73(b) Statement (when there is an assignee) <input type="checkbox"/> Power of Attorney10. <input type="checkbox"/> English Translation Document (if applicable)11. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations12. <input type="checkbox"/> Preliminary Amendment13. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) (Should be specifically itemized)<ul style="list-style-type: none">* Small Entity14. <input type="checkbox"/> Statement(s) (PTO/SB/09-12) <input type="checkbox"/> Statement filed in prior application, Status still proper and desired15. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed)16. <input checked="" type="checkbox"/> Other: Applicant hereby petitions for an extension of time whenever such a petition is required * A new statement is required to be entitled to pay small entity fees, except where one has been filed in a prior application and is being relied upon.
4. Oath or Declaration [Total Pages 10] <ul style="list-style-type: none">a. <input checked="" type="checkbox"/> Newly executed (original or copy)b. <input type="checkbox"/> Copy from a prior application (37 C.F.R. § 1.63(d)) (for continuation/divisional with Box 17 completed) [Note Box 5 below]i. <input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).	
5. <input type="checkbox"/> Incorporation By Reference (useable if Box 4b is checked) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered to be part of the disclosure of the accompanying application and is hereby incorporated by reference therein.	
17. If a CONTINUING APPLICATION , check appropriate box, and supply the requisite information below and in a preliminary amendment: <input type="checkbox"/> Continuation <input type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-part (CIP) of prior application No: _____ Prior application information: Examiner _____ Group / Art Unit: _____	

18. CORRESPONDENCE ADDRESS					
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Name (Print/Type)	Thomas R. Vigil	Registration No. (Attorney/Agent)	24,542
Signature	<i>Thomas R. Vigil</i>	Date	March 23, 2000

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Patent
USSN - New US Patent Application
Atty Docket 20037

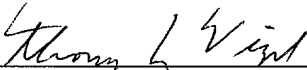
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Oscar Jimenez) Group Art Unit:
) Unknown
For: CATHETER WITH THERMORESPONSIVE DISTAL)
TIP PORTION) Examiner:
) Unknown
)
Serial No. (Unknown))
)
Filed: (Being Filed Herewith))

CERTIFICATE OF EXPRESS MAIL DEPOSIT

"Express Mail" Mailing Label No. EL 468140038 US
Date of Deposit: March 23, 2000

I hereby certify that this paper, or fee, is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and addressed to the Assistant Commissioner of Patents, Washington, D.C. 20231.

Thomas R. Vigil
(Typed or printed name of person mailing fee or paper)

(Signature of person mailing fee or paper)

The documents being enclosed with and being filed with this paper are:

1. New U.S Patent application (9 pages)
2. 1 sheet formal drawings
3. Executed Declaration from inventor (2 pages)
4. Executed Small Entity Declaration from inventor (1 page)
5. Application Transmittal Form
6. Fee Transmittal
7. Check for \$345.00
8. This Certificate of Express Mail Deposit
9. PTO Form 1449 & copies of 5 prior art references

**STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR**

Docket Number (Optional)
20037

Applicant, Patentee, or Identifier: Oscar Jimenez

Application or Patent No.: _____

Filed or Issued: March 23, 2000

Title: CATHETER WITH THERMORESPONSIVE DISTAL TIP PORTION

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- ☒ the specification filed herewith with title as listed above.
☐ the application identified above.
☐ the patent identified above.

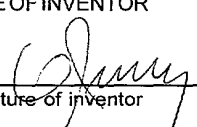
I have not assigned, granted, conveyed, or licensed, and am under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ No such person, concern, or organization exists.
☐ Each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern, or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

Oscar Jimenez
NAME OF INVENTOR

Signature of inventor
20 March 2000
Date

NAME OF INVENTOR

Signature of inventor

Date

NAME OF INVENTOR

Signature of inventor

Date

Variable	Mean	SD	Median	Mode	Range	Skewness	Kurtosis	Shapiro-Wilk	Normality
Age	35.2	12.5	32.0	30.0	20-55	0.15	2.10	0.98	Normal
Gender	1.2	0.4	1.0	1.0	1-2	0.05	0.10	0.99	Normal
Education	12.5	2.0	12.0	12.0	10-15	0.10	1.80	0.97	Normal
Income	1500	500	1200	1000	500-2500	0.20	2.50	0.95	Normal
Marital Status	1.5	0.5	1.0	1.0	1-2	0.05	0.10	0.99	Normal
Occupation	2.5	1.0	2.0	2.0	1-4	0.10	1.50	0.96	Normal
Health Status	1.8	0.6	1.5	1.5	1-3	0.05	0.10	0.99	Normal
Stress Level	3.5	1.5	3.0	3.0	2-5	0.15	2.10	0.98	Normal
Life Satisfaction	4.2	1.0	4.0	4.0	3-5	0.10	1.80	0.97	Normal
Resilience	3.8	1.2	3.5	3.5	2-5	0.15	2.10	0.98	Normal
Optimism	4.0	1.1	3.8	3.8	3-5	0.10	1.80	0.97	Normal
Emotional Stability	3.6	1.3	3.2	3.2	2-5	0.15	2.10	0.98	Normal
Self-Esteem	4.1	1.0	3.9	3.9	3-5	0.10	1.80	0.97	Normal
Life Satisfaction	4.2	1.0	4.0	4.0	3-5	0.10	1.80	0.97	Normal
Resilience	3.8	1.2	3.5	3.5	2-5	0.15	2.10	0.98	Normal
Optimism	4.0	1.1	3.8	3.8	3-5	0.10	1.80	0.97	Normal
Emotional Stability	3.6	1.3	3.2	3.2	2-5	0.15	2.10	0.98	Normal
Self-Esteem	4.1	1.0	3.9	3.9	3-5	0.10	1.80	0.97	Normal

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Marital Status	1.5	0.5	1.0	1.0	1-2	0.05	0.10	0.99	Normal
Occupation	2.5	1.0	2.0	2.0	1-4	0.10	1.50	0.96	Normal
Health Status	1.8	0.6	1.5	1.5	1-3	0.05	0.10	0.99	Normal
Stress Level	3.5	1.5	3.0	3.0	2-5	0.15	2.10	0.98	Normal
Life Satisfaction	4.2	1.0	4.0	4.0	3-5	0.10	1.80	0.97	Normal
Resilience	3.8	1.2	3.5	3.5	2-5	0.15	2.10	0.98	Normal
Optimism	4.0	1.1	3.8	3.8	3-5	0.10	1.80	0.97	Normal
Emotional Stability	3.6	1.3	3.2	3.2	2-5	0.15	2.10	0.98	Normal
Self-Esteem	4.1	1.0	3.9	3.9	3-5	0.10	1.80	0.97	Normal
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Occupation	1.0	0.3	1.0	1.0	1-3	0.05	0.10	0.99	Normal
Health Status	1.0	0.2	1.0	1.0	1-2	0.05	0.10	0.99	Normal
Stress Level	3.5	1.0	3.0	3.0	2-5	0.15	2.10	0.98	Normal
Life Satisfaction	4.0	0.8	4.0	4.0	3-5	0.10	1.80	0.97	Normal
Work-Life Balance	3.0	0.9	3.0	3.0	2-4	0.15	2.10	0.98	Normal
Family Support	4.5	0.7	4.5	4.5	4-5	0.05	0.10	0.99	Normal
Community Involvement	2.0	0.6	2.0	2.0	1-3	0.10	1.80	0.97	Normal
Personal Growth	3.0	0.8	3.0	3.0	2-4	0.15	2.10	0.98	Normal
Overall Well-being	3.5	0.9	3.5	3.5	2-5	0.15	2.10	0.98	Normal

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Health Status	1.0	0.2	1.0	1.0	1-2	0.05	0.10	0.99	Normal
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Work-Life Balance	3.0	0.9	3.0	3.0	2-4	0.15	2.10	0.98	Normal
Family Support	4.5	0.7	4.5	4.5	4-5	0.05	0.10	0.99	Normal
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Variable	Mean	SD	Median	Mode	Range	Skewness	Kurtosis	Shapiro-Wilk	Normality
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Education	12.5	2.0	12.0	12.0	10-15	0.10	1.80	0.97	Normal
Marital Status	1.5	0.5	1.0	1.0	1-2	0.05	0.10	0.99	Normal
Income	15000	5000	12000	10000	5000-25000	0.20	2.50	0.95	Normal
Occupation	1.0	0.3	1.0	1.0	1-3	0.05	0.10	0.99	Normal
Health Status	1.0	0.2	1.0	1.0	1-2	0.05	0.10	0.99	Normal
Stress Level	3.5	1.0	3.0	3.0	2-5	0.15	2.10	0.98	Normal
Life Satisfaction	4.0	0.8	4.0	4.0	3-5	0.10	1.80	0.97	Normal
Work-Life Balance	3.0	0.9	3.0	3.0	2-4	0.15	2.10	0.98	Normal
Family Support	4.5	0.7	4.5	4.5	4-5	0.05	0.10	0.99	Normal
Community Involvement	2.0	0.6	2.0	2.0	1-3	0.10	1.80	0.97	Normal
Personal Growth	3.0	0.8	3.0	3.0	2-4	0.15	2.10	0.98	Normal
Overall Well-being	3.5	0.9	3.5	3.5	2-5	0.15	2.10	0.98	Normal

CATHETER WITH THERMORESPONSIVE DISTAL TIP PORTION

BACKGROUND OF THE INVENTION

1. Field of the Invention.

The present invention relates to an improved thermoresponsive, soft/hard, 5 distal tip portion for any catheter that provides atraumatic contact with the lumen of a conduit. The distal tip portion is an improvement for many types of catheters used for both, the delivery and withdrawal of fluids and devices, especially by the trans-brachial approach. The applications include interventional guiding catheters, coronary catheters, drainage catheters, chemotherapy delivery catheters, and 10 neuroradiology catheters, among others. The thermoresponsive distal tip portion can be used as a sheath tip for a sheath introducer for peds. Also, it can be used as a sheath tip for a trans-brachial or neuro procedure.

2. Description of the Prior art.

Catheters are thin flexible tubes, which are introduced into a vein or artery and 15 guided to selected sites in the vascular system. Angiographic catheters are employed to inject contrast media into a vessel to visualize the shape, state, topography, functionality and other characteristics of the vessel for the purpose of diagnosing anatomic abnormalities of an organ and its conduits. Such catheters are used, for instance, to diagnose diseases of the heart and the circulatory system.

20 The guidance of a catheter within a tortuous vessel structure, such as a coronary artery and the arteries supplying the brain, often present difficult challenges. Efficient guidance of the distal portion of the catheter may be achieved by various means, including the use of a guidewire, essentially a long, slim and flexible wire or coil on which the catheter's lumen rides or slides to the desired location. An adjunct 25 to the guidewire, various pre-shaped distal configurations have been widely used for such applications as entry into the coronary arteries from the aorta, or for entering the Circle of Willis within the brain. The thermoresponsive distal tip portion for a catheter of the present invention is directed toward improving the performance of both guidewires and catheters with pre-shaped distal portions. For example, the soft tip 30 minimizes thrombus formation when scraping or damaging sensitive arterial walls during movement of the catheter within a blood vessel.

The introduction of a catheter into a vessel and its maneuvering within a vessel are less traumatic when the distal or leading portion of the catheter is soft at the time

the catheter comes in contact with the vessel. A soft distal portion of the catheter made of a polymeric or rubbery material in the range of about 35-40 Shore D hardness is desirable. Nevertheless, the degree of softness may present a problem while the catheter's soft distal tip portion is passed or forced through a percutaneous 5 introducer system including an introducer catheter having a hemostasis valve. The introducer facilitates the percutaneous insertion of the catheter by eliminating the need for a surgical cut-down to the vessel, and the hemostasis valve usually employs a membrane for the catheter to pass through without permitting blood to exit out of the vessel and from the body. When the distal portion is soft and rubbery, it may 10 become severely deformed by the force needed for its insertion through the homeostasis valve. When the soft polymeric or rubbery distal portion demands a great deal of force to be passed through the introducer and hemostasis valve, the soft portion may be damaged, torn or even separated from the rest of the catheter. The excessive traction force or friction is the consequence of the soft rubbery interface 15 with the percutaneous introducer housing, hemostasis valve and cannula. If the entire soft distal end or even a part of it were to detach due to excessive traction, then this may cause serious medical complications, even surgical intervention may become necessary during the catheterization procedure.

A variety of catheter and soft distal tip improvements have been made since 20 the first human catheterization was performed by Forssmann in 1929. An example of such improvement is taught by the Horrigan et al. in US Patent 5,811,043 as well as others. Nevertheless, the prior art of soft distal ends or tips takes into consideration a virtual steady state softness of the distal end within a temperature range of 15 to 40°C. In effect, the soft distal tip portion of the catheter remains soft 25 at both room temperature and body temperature. Certain materials employed for the distal tip portion become even softer at body temperature than at room temperature and lose strength as they become softer. This characteristic may pose a further problem upon completing the catheterization procedure and retrieving the catheter from the body through the percutaneous introducer system, as part of it may tear off 30 and remain inside the vessel.

Other U.S. Patents of interest with respect to thermoresponsive materials are listed below:

U.S. Patent No.

Patentee

5,957,966

Schroeppel

5,997,526

Giba et al.

6,001,078

Reekers

6,002,969

Machek et al.

5

SUMMARY OF THE INVENTION

The atraumatic benefits derived by using a catheter with a soft distal tip portion may be offset by the risk of difficulties with the integrity of that portion during catheter introduction and retrieval through a percutaneous introducer system. It is therefore desirable to have a catheter distal terminal whose hardness is approximately equal
 10 to the hardness of the catheter body (about 72 Shore D hardness) at room temperature, to allow safe and fast introduction through a percutaneous introducer system, but that distal portion should become softer (35-40 Shore D hardness) shortly after it enters the vessel in the body where the temperature is about 37°C. This thermoresponsive distal terminal changes its physical properties as a function of
 15 temperature without changing the general properties of its material. Thus, the passage of the catheter's distal tip portion through the percutaneous introducer is facilitated without risking its integrity, yet the distal part of the catheter becomes soft after passing through the percutaneous introducer system and as it comes into direct contact with a fluid filled conduit, such as a blood vessel, and touches the interior of
 20 the vessel. The thermoresponsive soft distal tip portion may become more lubricious as it softens; hence removal of the catheter through the percutaneous introducer is simplified and more secure.

The thermoresponsive raw material for the construction of the catheter's distal tip portion may be chosen to be REMEMOMER™, which is available from Mitsubishi
 25 Polyurethane, Memory Products Division, 57 Commerce Drive, Brookfield, CT 06804, or any similar material with a critical transition temperature of about $T_c = 31^\circ\text{C}$. This material manifests a controlled hardness reduction from 72 Shore D (hard) to 35 Shore D (soft) at 31° . Below 31°C temperature the material retains its hardness in the range of 72-75 Shore D. The material becomes and remains soft above 31°C .
 30 Mitsubishi MM-3500 polyurethane, sold under the trademark REMEMOMER™, or similar thermoresponsive materials may be used for this application.

Catheters within the body are often positioned under fluoroscopic guidance; hence it is necessary for the distal portion of the catheter to be well defined in the

fluoroscopic image. Toward that objective, the thermoresponsive material must contain a radiopaque substance to view it under X-rays. Rememomer™ or other similarly thermoresponsive polymers must be loaded or compounded with a radiopaque medium such as barium sulfate, bismuth subcarbonate or one of a variety
5 of metal powders, to enhance their radiopacity. This is achieved by heating the polymer to its melting point and mixing with it the selected radiopaque medium. The final radiopaque compound is molded to form the soft distal portion of a catheter, using conventional insert molding or welding techniques.

The present invention also allows the use of other polymeric materials, such
10 as harder conventional polyurethane resins to dilute the softening properties of the thermoresponsive material. Hence, a specific softness may be titrated as required for a specific application. The titrated material may serve to relieve the zones of stress concentration typically associated with hard-to-soft transitions along the longitudinal axis of a catheter with a soft distal portion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of a catheter constructed according to the teachings of the present invention having a thermoresponsive soft/hard distal tip portion.

FIG. 2 are graphs of the temperature versus durometer hardness for the 5 catheter and for the distal tip portion.

FIG. 3 is a sectional view of the catheter and is taken along line 3-3 of FIG. 1.

FIG. 4 is a sectional view of the joint between the distal end of the catheter and the distal tip portion and is taken along line 4-4 of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

Referring to the drawings in greater detail, there is illustrated in FIG. 1 a catheter assembly 10 constructed according to the teachings of the present invention including a catheter 12, a Luer™ connector 14 at a proximal end 16 of the catheter 12 and a thermoresponsive, soft/hard distal tip portion 18 fixed to a distal end 20 of the catheter 12.

The hardness of the thermoresponsive material from which the distal tip portion 18 is made is shown as a function of temperature in FIG. 2. The temperature transition region is approximately 5°C wide.

Furthermore, the thermoresponsive material may also be used as a jacket 22 to encapsulate a stiffer and harder wire-braided catheter body 24 as shown in FIG. 3. The catheter body 24 includes an inner extrusion 26, a wire braid 28 on the outer surface 30 of the inner extrusion, an outer extrusion 32 and the jacket 22 made of a thermoresponsive material on the outer surface 34 of the outer extrusion 32. This wire-braided construction is often employed to increase the internal pressure limit for a catheter 12 with the goal to increase flow in the catheter 12 without any risk of damage to the catheter structure or the surrounding vessel. The wire-braided structure also improves the torque response of the catheter: when its proximal portion Luer™ connector 14 is rotated by the physician and its distal end portion, distal tip portion 18, follows closely that rotation, despite the tortuosity of the path. The distal tip portion 18 of such a catheter needs to be soft and lubricious to prevent damage to the vessel when the catheter 12 is rotated. In this case the softer material may be extruded and thereby bonded over a harder extrusion or braiding over a relatively long segment of the catheter 12, possibly even the entire length of the catheter may be jacketed in the soft material.

Radiopacity through compounding may be omitted from such a configuration as the wire-braiding does serve as a radiopaque structure.

If additional radiopacity is desired, the thermoresponsive material may be loaded or compounded with a radiopaque medium such as barium sulfate, bismuth subcarbonate or metal powders. The radiopacified thermoresponsive material is used as the jacket 22 to encapsulate the catheter 12 as shown in FIG. 3.

In this configuration, the thermoresponsive distal tip portion 18 may be welded or insert molded to a tapered end 20 of the catheter 12, as shown in FIG. 4.

The thermoresponsive encapsulation may be accomplished using Mitsubishi Rememomer™ MM-3500 polyurethane or any similar thermoresponsive material. Unlike conventional catheters, the thermoresponsive encapsulation hardness is 72-75 Shore D hardness at room temperature and becomes softer to 35 Shore D hardness
 5 at 31 °C. The soft encapsulation provides an atraumatic, lubricious surface to protect the tissues during catheter manipulation within the vasculature and prevents trauma during characterization. An example of the jacket encapsulation is shown in FIG. 3.

With the catheter assembly 10, the thermoresponsive distal tip portion is inserted through a hemostasis valve of an introducer catheter system and into an
 10 introducer catheter until the distal tip portion reaches a blood vessel. Then, further insertion is halted until a short time has passed, e.g., for a few minutes, and possibly up to 5 minutes. This gives the distal tip portion 18 time to heat up and soften. Now the soft distal tip can be inserted into and through the blood vessel to a desired location for performing a medical procedure.

15 From the foregoing description, it will be understood that the tip distal portion 18 of the present invention has a number of advantages, some of which have been described above and others of which are inherent in the invention. Also, modifications can be made to the tip distal portion 18 and the catheter assembly 10 of the present invention without departing from the teachings of the invention.
 20 Accordingly, the scope of the invention is only to be limited as necessitated by the accompanying claims.

CLAIMS**I CLAIM:**

1. A catheter assembly comprising a tubular body having a proximal end and a distal end and a thermoresponsive distal tip portion fixed to said distal end of said catheter.
2. The catheter assembly of claim 1 wherein said thermoresponsive material is harder at temperatures below a critical temperature and softer at temperatures above said critical temperature.
3. The catheter assembly of claim 2 wherein said critical temperature is approximately 31°C.
4. The catheter assembly of claim 2 wherein said distal tip portion has a Shore hardness of 72-75 D at temperatures below said critical temperature for facilitating the pushing of said catheter into an introducing catheter.
5. The catheter assembly of claim 2 wherein said distal tip portion has a Shore hardness of 32-35 D at temperatures above said critical temperatures.
6. The catheter assembly of claim 1 wherein said distal tip portion is made of a thermoresponsive polyurethane.
7. The catheter assembly of claim 1 wherein said distal tip portion has a radiopaque material therein.
8. The catheter assembly of claim 1 wherein said tubular body is coated with a jacket made of said thermoresponsive material,
9. The catheter assembly of claim 1 wherein said tubular body is a wire braided body comprising an inner tubular extrusion, a wire braid on the outer surface of said inner tubular extrusion and an outer tubular extrusion extruded over said wire braid.
10. The catheter assembly of claim 1 wherein said distal end of said catheter is tapered and said distal tip portion is welded on or molded on said tapered distal end of said catheter.

The catheter assembly comprises a tubular body having a proximal end and a distal end and a thermoresponsive distal tip portion fixed to the distal end of the catheter.

The catheter assembly comprises a tubular body having a proximal end and a distal end and a thermoresponsive distal tip portion fixed to the distal end of the catheter.

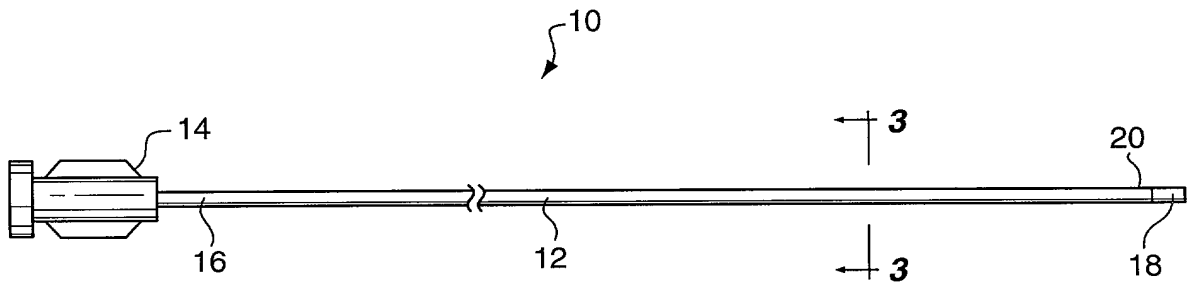


FIG. 1

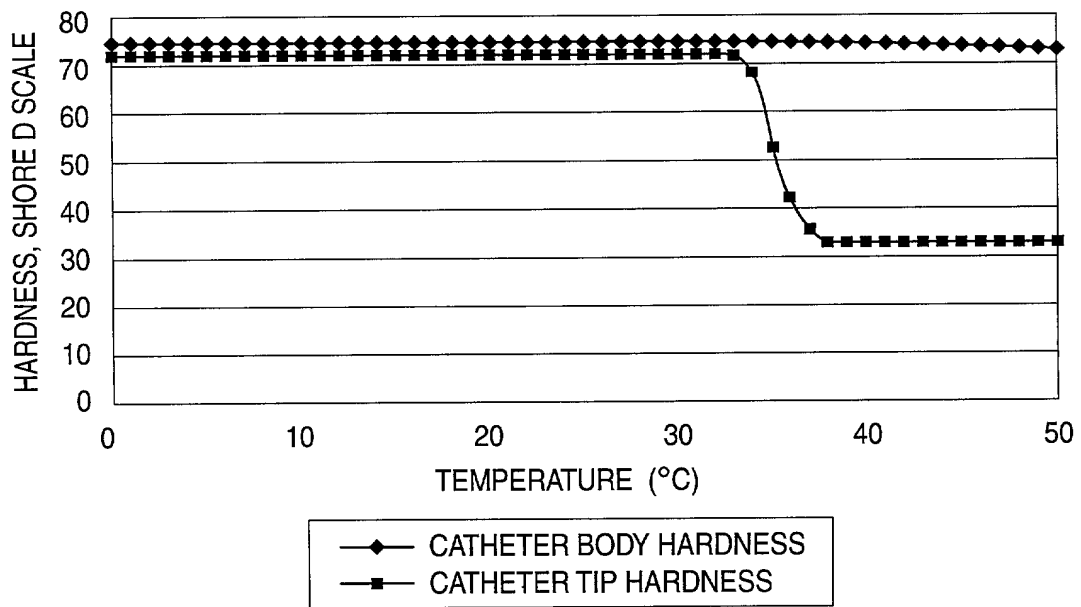


FIG. 2

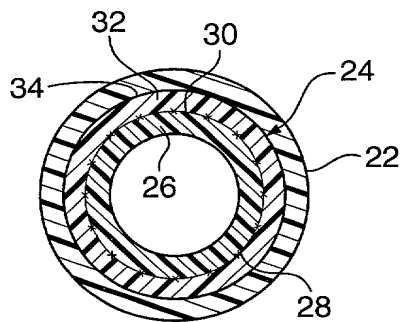


FIG. 3

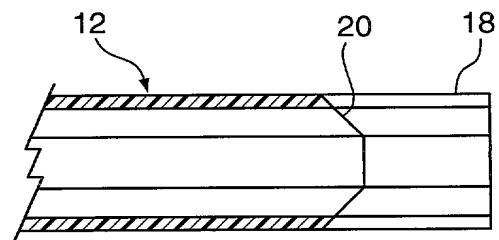


FIG. 4

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**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	20037
First Named Inventor	Oscar Jimenez
COMPLETE IF KNOWN	
Application Number	/
Filing Date	March 23, 2000
Group Art Unit	Unknown
Examiner Name	Unknown

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CATHETER WITH THERMORESPONSIVE DISTAL TIP PORTION

the specification of which (Title of the Invention)

☒ is attached hereto
OR

☐ was filed on (MM/DD/YYYY) as United States Application Number or PCT International

Application Number and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

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I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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Name	Registration Number	Name	Registration Number
Thomas R. Vigil	24,542		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label

OR ☐ Correspondence address below

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Country	US	Telephone	(847) 382-6500	Fax	(847) 382-6895

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))		Family Name or Surname					
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Inventor's Signature				Date	3/20/2000		
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Post Office Address							
City	Coral Gables	State	FL	ZIP	33134	Country	US

☐ Additional information is provided on the supplemental Additional Information sheet PTO/SB/02A attached hereto.